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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
GAKH, YELENA G	

ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 01/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/092,837	BACH ET AL.	
	Examiner	Art Unit	
	Yelena G. Gakh, Ph.D.	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 March 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 March 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *08/26/02, 09/02/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Priority

1. This application filed under former 37 CFR 1.62 lacks the necessary reference to the prior application. A statement reading "This is a continuation of Application No. 09/415,796, filed 10/11/1999." should be entered following the title of the invention or as the first sentence of the specification. Also, the current status of the parent nonprovisional application(s) should be included.

Specification

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. The specification is objected to as not being written in "such full, clear, concise, and exact terms" as to enable any person skilled in the art to practice the invention in its best mode.

Specifically, the "Summary" does not provide a clear idea of the essence of the invention. Definition of the method as "a method of performing a determination of an item of interest in a sample using a single structure" raises a question of why such cumbersome definition could not be simplified to a conventional "a method for detecting an analyte in a sample using a single structure"? If this is not what is meant by the definition given in the Summary, then it is not apparent, what actually is meant. From the Summary it is completely unclear, how this "determination" is performed. It is not clear, what the whole expression "a sample is provided accessible to the single structure" might mean. What is the "single structure"? Can a single conveyer with several different stations be considered "a single structure"? Also, what kind of a sample would be *inaccessible* to the structure? It is not clear, where the sample is transferred *from* to the first container? (If it is transferred, it is supposed to be transferred *from* one place to

another). It is not apparent, if there is any connection between adding a reagent to this container and separation of "the item of interest". If there is no connection, then it is not clear, why the reagent is added, and how "the item of interest" is separated, or why it could not be separated before adding the reagent. The following expression is so confusing that the examiner fails to understand its meaning: "content of the second container is brought to a first temperature different form a temperature of the first process path in the second process path". What is "a temperature of the first process path in the second process path"? How the item of interest in the second container is detected? Why the temperature should be different for the item to be detected? The Summary of the invention is written in a very confusing and unclear language.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 19-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 19 recites separating "an item of interest" from the contents of the container, varying the temperature of the content in the container and detecting the "item of interest in the container", while the item is absent from the container, since it was separated from the content of the container in the first place. No one of ordinary skill in the art can practice such method.

6. Claims 1-26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the method involving separation of the analyte ("item of interest") bound to the solid phase support, including magnetic beads, does not reasonably provide enablement for any other method. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The specification does not disclose any other ways of

separating "the item of interest" from the contents of the first container in the first process path besides binding the "item of interest" with a specific ligand attached to the solid phase support, including magnetic particles, and separating these particles with attached analyte in the first process path. All other separation techniques (chromatography, electrophoresis, etc.) involve employing additional devices, which are not disclosed in the specification as being capable for installing in the single structure of the instant application with a reasonable simplicity.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Preamble of all independent claims (1, 12, 19, 25 and 26) is written in such indefinite terms, that it is difficult to understand the field of the invention. What is "a determination of an item of interest in a sample using a single structure"? What determination, quantitative or qualitative is meant here? Is "an item of interest" just an analyte? What is "a single structure"?

Claim 1 recites as step (a) "providing a sample accessible to the single structure". It is not clear, what type of the sample should be provided so that it would be "accessible to the single structure". No specific requirements for such sample are disclosed in the specification, which makes the step (a) unclear. The same recitation raises a question of what type the single structure should be so that it requires a special sample, which would be accessible to this structure? No specific description of such single structure is provided in the specification. In step (c) it is not clear, where is the sample transferred from? It is further unclear, if there is any connection between steps (d) and (f), and if there is, which connection that might be. If there is no connection between steps (d) and (f), then it is not clear, what type of a reagent is added to the first container and why. If there is a connection, it is not clear, if the "item of interest" in step (f) is exactly the same as the one recited in the preamble of the claim; it may be assumed that the "item" is changed as a result of the reaction with the reagent. The step (h) is completely unclear, as it is not apparent, what is "a temperature of the first process path in the second process path"? Also, it is not clear, what the content of the second container might be besides the "item of

interest" transferred from the first container. It is further unclear, how detecting "the item of interest" is performed. It is worth noting that "determining" and "detecting" are not synonyms.

In claims 2 and 7 the term "a second first container" does not have any sense. The container can be either first or second. In claim 2 it is completely unclear, how the "item of interest" is detected, and if there is any connection between steps (k) and (l).

Claims 3 and 4 are not clear as to why the first or second containers should be sealed just for removing the seal in the next step.

Claim 5 is not clear as to how the exposure of contents of the first or second containers may be reduced if not by sealing them.

In claim 6 it is not clear if the second temperature is the same as the temperature of the content of the container in the first path.

In claim 7 it is not clear, if the reagent has any effect on the "item of interest", and if it does, then how does the item of interest remain the same?

Claim 9 is completely unclear. What does it mean, "a determination of an item of interest comprises at least one process"? How the method of determination may not comprise any process? What is "discerning determinations to be performed by the single structure"? What does it mean and how is it done?

In claim 10 it is not clear, how "allocating an element of the single structure" is done. It is not clear, what type of a physical process is meant by this step.

Claim 11 is unclear. Does it mean "providing a duplicate element of the single structure"?

The rest of the claims have similar problems.

Also, claim 19 is unclear as to what method it recites. It is not apparent, how "**an** item of interest" is separated (is this a different "item of interest" than recited in the preamble?), and if it is separated from the content of the container, then what is the purpose of temperature manipulations with the content of the container, if there is no "item of interest" in this container? Moreover, how can it be detected in the container, if it is not there? The claim is completely unclear.

The subject matter of claims 25 and 26 is completely unclear. It s not clear, what might be "an item of interest in a sample", why the sample should be transferred from one container to

another, why the temperature of the content in the containers should be changed, and how this can facilitate detecting "the item of interest". Also, "determination" and "detecting" are not synonyms.

Double Patenting

9. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim 8 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim1 of prior U.S. Patent No. 6,413,780 B1. This is a double patenting rejection.

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7 and 9-11 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,413,780 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other

because "at least one of the plurality of second process sub-paths of the second process path" of the parent case is a more specific limitation than "a second process path" of the instant application.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. **Claims 25-26** are rejected under 35 U.S.C. 102(b) as being anticipated by Hoskins et al. (US 3,883,305, IDS).

Hoskins teaches a method of automatic chemical analysis, comprising transferring a sample to a first container in a first process path 5, incubating it at the first temperature, transferring the sample from the first container to the second container in the second path 26 and bringing content of the second container to a second temperature different from the first one using a heater 30, and detecting the item of interest in the second path with a detector 43.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

15. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

16. **Claims 1-18** are rejected under 35 U.S.C. 103(a) as being unpatentable over Choperena et al. (US 5,380,487) in view of Hoskins.

Choperena discloses a device and method for automatic chemical analysis, the method comprising placing a plurality of containers in a first process path (54) on a single structure, transferring samples comprising analytes and reagents (32) into the containers, mixing them, separating analytes, transferring separated analytes in the containers in the second process path (60) and detecting the analyte ("the item of interest") (col. 9 and 10). The washing station can be on the same path as a detector, or on the first process path (col. 17, lines 3-15, Figure 7). Controlled different temperatures are used for keeping reagents at a refrigerator temperature, incubating reaction mixtures at higher temperatures and detecting the analytes (col. 9, lines 45-70). A detailed description of scheduling of the events according to the processes is presented in the Summary of the Invention.

While Choperena does not specifically disclose sealing the vessels between the measurements, it is a conventional and obvious feature of any analysis, which makes it obvious for any routineer in the art to imply.

Choperena discloses transferring containers (vessels) from one path to another, rather than transferring samples. Transferring samples from one container into another within different

stations is a conventional feature of an automated analysis utilizing automated analyzers, as taught by e.g. Hoskins.

It would have been obvious for any routineer in the art to slightly modify Choperena's method by implying transferring samples from one set of containers to a different set of containers in different paths, as taught by Hoskins, because it is a conventional feature of analysis using a variety of automated analyzers, and because it increases the efficiency of the analysis, since using aliquots of the same sample allows conducting several tests or measurements on the same sample.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yelena G. Gakh, Ph.D. whose telephone number is (571) 272-1257. The examiner can normally be reached on 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Yelena G. Gakh
12/29/04